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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/916,711	07/27/2001	Rathbun Rhodes	1146-8	8240

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EXAMINER

Nasser, Robert L

ART UNIT PAPER NUMBER

3736

DATE MAILED: 12/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/916,711	RHODES ET AL.	
	Examiner	Art Unit	
	Robert L. Nasser	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12-15 and 21-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12-15 and 21-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/22/2004 has been entered.

Applicant's election of species I, claims 1-10, 12-15, and 21-33 in Paper No. 11 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 21 and 24-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Ito 5,384,028. In figure 2, Ito shows a biosensor with a sapphire (glass) housing, substrate 11, a working electrode 13, a counter electrode 12, and a reference electrode 14, where the counter electrode has a larger area than the working electrode, and a multi-region membrane, a lactate-oxidase membrane on the working electrode and a albumin membrane on the other electrodes. With respect to claim 24, the counter electrode is made from Au, or gold. With respect to claims 25-28, by examining

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figure 2, it seems that the counter electrode is 2.5 times the size of the working electrode. As to claim 29, Ito measures glucose or lactate in a biological fluid.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 5-10, 12-15, and 22-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heller et al 6392161 in view of Shults et al 6001067 and Nagata 4871440. Heller et al shows an electrode 2 under a multi-layered membrane 8, 10, 12, and 1. In column 7, lines 65-column 8, line 17, Heller et al states that it can make glucose measurements by monitoring the rate of change of current in an electrode system and states that a reference and a counter electrode are necessary for such a measurement. Heller et al does not show the structure of the three electrode system. However, Shults et al shows such a three electrode glucose sensing device that includes a housing made from polyethylene, (see column 9, lines 35-36), where the housing includes a sensing area having a working reference and counter electrode 20, 21, and 22, and a multi-layer membrane over the electrode area. It would therefore have been obvious to modify Heller et al to use the structure of Shults, as it is merely the substitution of one known equivalent structure for another. The areas of the counter and working electrodes appear to be the same. However, Nagata et al shows a 3 electrode system for measuring glucose concentration, where the counter electrode is made larger than the working electrode (see figures 9 and 10) to stabilize the potentials

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of the electrodes. Therefore, it would have been obvious to modify the above combination to use such an arrangement of working and counter electrodes, so as to stabilize the potential of the electrodes. The examiner notes that Nagata does not disclose the relative sizes of the electrodes. However, by examining the cover figure, the working electrode has a diameter of 5 mm, and the counter electrode has an inner diameter of 14 and an outer diameter of 21 mm. Using these dimensions, the area of the counter electrode is 5 (half circle) to 10 (full circle) times the area of the working electrode. In Shults, the multi-layer membrane includes (from farther away to adjacent to electrodes) an angiogenic layer which is equivalent to the disclosed cell disruptive domain, a second layer which is the bioprotective layer, which is equivalent to the cell impermeable domain, then an enzyme membrane comprised of a resistance layer, an enzyme layer, an interference layer, and a electrolyte (i.e. hydrogel layer). The examiner notes that with respect to claim 6, the first domain of Shults is the angiogenic layer and the bioprotective layer. With respect to claim 7, the resistance layer of Shults is the second domain and excludes glucose. With respect to claims 8 and 9, the enzyme layer of Shults is the third domain. Both the working and counter electrodes are made from platinum (see column 9, line 62- column 10, line 2). The device of Shults is implanted. Shults further teaches the recited method.

Claims 1, 2, 5-10, 12-15, and 22-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shults et al 6001067 in view of Ito 5,384,028. Shults et al shows biosensor for analyte monitoring including a housing made from polyethylene, (see column 9, lines 35-36), where the housing includes a sensing area having a working

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reference and counter electrode 20, 21, and 22, and a multi-layer membrane over the electrode area. The areas of the counter and working electrodes appear to be the same. However, Ito in figure 2 shows a system where the counter electrode is made larger than the working electrode. Therefore, it would have been obvious to modify the above combination to use such an arrangement of working and counter electrodes, as it is merely the substitution of one known configuration of electrodes for another. The examiner notes that Ito does not disclose the relative sizes of the electrodes. However, by examining figure 2, it appears that the counter electrode has an area between 2 and 100 times that of the working electrode. In Shults, the multi-layer membrane includes (from farther away to adjacent to electrodes) an angiogenic layer which is equivalent to the disclosed cell disruptive domain, a second layer which is the bioprotective layer, which is equivalent to the cell impermeable domain, then an enzyme membrane comprised of a resistance layer, an enzyme layer, an interference layer, and an electrolyte (i.e. hydrogel layer). The examiner notes that with respect to claim 6, the first domain of Shults is the angiogenic layer and the bioprotective layer. With respect to claim 7, the resistance layer of Shults is the second domain and excludes glucose. With respect to claims 8 and 9, the enzyme layer of Shults is the third domain. Both the working and counter electrodes are made from platinum (see column 9, line 62- column 10, line 2). The device of Shults is implanted. Shults further teaches the recited method.

Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heller et al in view of Shults et al and Nagata as applied to claims 1, 2, 5-10, 12-15, and

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22-33 above, and further in view of Schulman et al 6119028. Shults does not teach a material for the resistance layer. However, Schulman shows a membrane 24 that behaves in the same manner of the resistance layer. Membrane 24 of Schulman is made from silicone, which is disclosed to be the material used for the oxygen antenna domain. Hence, it would have been obvious to modify the above combination to make the resistance layer from silicone, as it is merely the substitution of one known material for another. Hence, membrane 24 is an oxygen antenna. With respect to claim 7, membrane 24 of Shults is a glucose exclusion membrane

Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shults et al in view of Ito as applied to claims 1, 2, 5-10, 12-15, and 22-33 above, and further in view of Schulman et al 6119028. Shults does not teach a material for the resistance layer. However, Schulman shows a membrane 24 that behaves in the same manner of the resistance layer. Membrane 24 of Schulman is made from silicone, which is disclosed to be the material used for the oxygen antenna domain. Hence, it would have been obvious to modify the above combination to make the resistance layer from silicone, as it is merely the substitution of one known material for another. Hence, membrane 24 is an oxygen antenna. With respect to claim 7, membrane 24 of Shults is a glucose exclusion membrane

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heller et al in view of Shults et al and Nagata et al as applied to claims 1,2, 5-10, 12-15, and 22-33 above, and further in view of Ward et al 6,212,416. Ward et al shows an analyte sensing device with a ceramic housing. Hence, it would have been obvious to modify

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the above combination to use ceramic, as it is merely the substitution of one known equivalent material for another.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shults et al in view of Ito, as applied to claims 1,2, 5-10, 12-15, and 22-33 above, and further in view of Ward et al 6,212,416. Ward shows an analyte sensing device with a ceramic housing. Hence, it would have been obvious to modify the above combination to use ceramic, as it is merely the substitution of one known equivalent material for another.

Applicant's arguments filed 11/22/2004 have been fully considered but they are deemed moot in view of the new grounds of rejection

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser whose telephone number is (571) 272-4731. The examiner can normally be reached on Mon-Fri, variable hours.

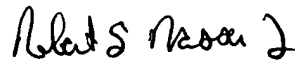
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert L. Nasser
Primary Examiner
Art Unit 3736

RLN
December 15, 2004



ROBERT L. NASSER
PRIMARY EXAMINER